

REMARKS

Appreciation is hereby expressed to Examiner Lillian Di Nola-Baron for the detailed Office Action. Pursuant to that Office Action, the claims have been amended to more definitely set forth the invention and obviate the rejections. For example, in Claim 17 the word “dissolution” has been changed to “dissociation” to correct a spelling error. Support for the corrected spelling appears in the Specification on page 4, line 10, and page 6, line 13. In addition, the dependency of Claims 18 and 22 has been changed from Claim 1 to Claim 17. Further, the dependency of Claims 19-21 has been changed from Claim 2 to Claim 18, and the dependency of Claims 23-25 has been changed from Claim 6 to Claim 22. The present amendment is deemed not to introduce new matter. Claims 17-25 are pending in the present application, Claims 1-16 having been cancelled in a preliminary amendment.

Reconsideration is respectfully requested of the rejection of Claims 23-25 under 35 U.S.C. § 112, second paragraph, as being a definite. The dependency of Claims 23-25 has been changed as indicated above. It is therefore believed that the rejection is moot. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 17-25 under 35 U.S.C. § 102(a) as being anticipated by Sun, et al. (U.S. Patent 6,678,554).

At the outset, it is respectfully urged that Sun, et al. fail to disclose a structure for iontophoresis comprising an electrically conductive layer containing at least one of partially ionized active ingredients and a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation, and an electrode for supplying electric current to the electrically conductive layer, as now called for in the claims herein.

In the rejection the Examiner contends that “With regard to the limitations in the claims, that the polymer has a polarity selected for controlling pH variations, the patent teaches that polymers, such as Eudragit S or Eudragit E, maintain the pH of the electrode medium (See column 12, lines 38-65)”. However, it is respectfully submitted that a fair reading of the Sun, et al. reference would lead to the conclusion that the polymer such as Eudragit S or Eudragit E may be used to prevent an increase in the pH of the electrode medium in the fluid reservoir 100 rather than maintaining the pH of the electrode medium. This is because in Sun, et al., active agent reservoir 120 containing an active agent in solution during electrotransport delivery is separated by semipermeable membrane 108 from the fluid reservoir 110 (See Fig. 1 and column 8, lines 24-27).

Further, the semipermeable membrane 108 inhibits the active agent from contacting the surface of electrode 112 as disclosed in column 8, lines 43-44, of Sun, et al. It is respectfully submitted that a fair reading of Sun, et al. would lead one of ordinary skill in the art to conclude that polymers may be used to prevent an increase in the pH of the electrode medium in the fluid reservoir 10 (i.e., 100) as described in Sun, et al. in column 12, lines 24-27. Additionally, it is respectfully submitted that one of ordinary skill in the art would reasonably conclude that Sun, et al. does not disclose using an agent for controlling pH variations in the active agent reservoir 120.

In contradistinction, in the present invention there is no semipermeable membrane installed between the active agent reservoir and the fluid reservoir as in Sun, et al. Instead, the device of the present invention includes an electrically conductive layer containing at least one of partially ionized active ingredients and a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variations.

In the present invention, although the electrically conductive layer (102) is to be directly attached to the skin as shown in Fig. 1 “by using a water swelling polymer showing pH dependent solubility in a electrically conductive layer using iontophoresis, without decreasing the drug delivery rate, enabling safe drug delivery to the living body, and thus we completed the present invention”. (See Specification herein, page 7, lines 10-14) It is respectfully submitted that these effects of the present invention cannot be derived from the device disclosed by Sun, et al. because the pH variations control in Sun, et al. is not carried out in the active agent reservoir 120, but only in the fluid reservoir 110 as discussed above.

In view of the foregoing, it is respectfully submitted that Sun, et al. fail to disclose the structure as now called for in the claims herein and, specifically, the water swelling polymer having polarity selected considering the dissociation of the active ingredient for controlling pH variations in the fluid reservoir. For these reasons, it is respectfully submitted that Sun, et al. fail to disclose a structure having the limitations of the claims now in the application. Consequently, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 17-25 under 35 U.S.C. § 102(e) as being anticipated by Suzuki, et al.

The inventors herein investigated the pH adjusting ingredient for iontophoresis which would be excellent in drug relief without decreasing the transfer rate or uniformity and dispersion at preparation as well as any influence on the base components. As a result of this investigation, the applicants herein found that good electrical conductivity as well as efficient and stable drug absorption for a long period of time can be obtained by controlling pH scattering, uniformity and

dispersion at preparation, further pH variation during energizing with current, by using a water swelling polymer showing pH dependent solubility in an electrically conductive layer using iontophoresis, without decreasing the drug delivery rate and thereby enabling safe drug delivery to a living body. (Specification, page 7, lines 2-14)

The Examiner predicates the rejection herein on the Doctrine of Inherency, asserting that “The pH adjusting function claimed by Applicant is inherent.”

Applicants respectfully submit that this rejection fails for several reasons as follows:

First, there is only a broad disclosure of numerous additives which may be used with the respective starting materials as appropriate in the iontophoresis. In this connection, Suzuki, et al. mentioned that in their production method additives can be used such as “protolytic enzyme inhibitors, isotonizing agents, preservatives, antioxidants, pH regulators, plasticizers, surfactants, osmolarity enhancers and other additives may be added as appropriate”. (Column 7, lines 14-19)

There is no disclosure in Suzuki of an iontophoresis device comprising an electrically conductive layer containing at least one of partially ionized active ingredients and a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation, and an electrode for supplying electric current to the electrically conductive layer. On the contrary, that teaching or suggestion comes only from the present application and constitutes an important element or aspect of the present invention.

Failing the disclosure of the specific water swelling polymer of the present invention for controlling pH variation, it is respectfully submitted that the disclosure of Suzuki, et al. fails to anticipate or render unpatentably obvious the subject matter as now called for in the claims herein.

Secondly, it is respectfully submitted that the Doctrine of Inherency does not apply in this

particular case. The issue presented in this rejection is whether the conditions for application of the Doctrine of Inherency are satisfied in the present case.

Applicants respectfully submit that those conditions are not satisfied.

In order for prior art such as Suzuki, et al. to anticipate, the inherency must be certain. Glaxo, Inc. v. Novopharm Ltd., 830 F Supp 871, 29 USPQ 2d 1129 (EDNC 1993); and Ex parte Cyba, 155 USPQ 756 (POBA, 1966). The fact that a prior art article may inherently have the characteristic of the claimed product is not sufficient. Ex parte Skinner, 2 USPQ 2d 1788 (BPAI, 1986).

In the present case, Suzuki, et al. disclose using pH regulators “as appropriate”. However, Suzuki, et al. do not disclose when the use of pH regulators are appropriate or that the use of pH regulators will have any effect whatever. Moreover, Suzuki, et al. fail to disclose that the pH can be controlled with a water swelling polymer having polarity selected considering the dissociation of the active ingredient so as to control pH variation during the electrophoresis.

For these reasons, it is respectfully submitted that Suzuki, et al. do not anticipate the claims now in this application based on the Doctrine of Inherency. This is because the inherency is not certain nor is there sufficient disclosure of the particular type of water swelling polymer which can be used to achieve the desired effect called for herein. For these reasons, it is respectfully submitted that the rejection based on Suzuki, et al. fails as a matter of law in view of the above authorities. Consequently, the Examiner would be justified in no longer maintaining this rejection.

Reconsideration is respectfully requested of the rejection of Claims 17-25 under 35 U.S.C. § 102(e) as being anticipated by Iga, et al.

The Examiner predicates this rejection on the Doctrine of Inherency asserting that the pH adjusting function claimed by Applicant is inherent in the disclosure of Iga, et al. Applicants respectfully submit that the Examiner's reliance on the Doctrine of Inherency is misplaced in this instance for several reasons. First, the broad disclosure of the addition to the hydrophilic gel of pH regulators fails to suggest the use of a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation in an iontophoresis device.

It is respectfully submitted that there is no disclosure whatever in Iga, et al. of the use of the water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation in an iontophoresis device. On the contrary, that teaching comes only from the present application and constitutes an important element or aspect of the present invention. Consequently, it is respectfully submitted that the disclosure of Iga, et al. does not anticipate or render unpatentably obvious the subject matter now called for in the claims herein.

Secondly, the issue presented here is whether the rejection satisfies all of the conditions required for an inherency rejection. Applicants respectfully submit that it does not.

As discussed above, in order for the prior art to anticipate on the ground of inherency, the inherency must be certain. Glaxo, Inc. v. Novopharm, Ltd., 830 Fed Supp 871 (EDNC 1993). Further, the fact that a prior art device or article may inherently have the characteristics of the claimed product or apparatus is not sufficient. Ex parte Skinner, 2 USPQ 2d 1788 (BPAI, 1986)

In the present case, Iga, et al. indicate that "PH regulators can be added" to the hydrophilic gel. Thus, it is respectfully submitted that the disclosure of Iga, et al. is insufficient for an inherency rejection since the alleged inherency is not certain. This is because Iga, et al. merely indicate that pH regulators can be added rather than must be added to achieve the desired results.

Therefore, the rejection based on Iga, et al. is not a sufficient basis in law to support a rejection based on inherency in view of Ex parte Skinner above. For these reasons, it is respectfully submitted that the inherency rejection predicated on Iga, et al. fails as a matter of law in view of the above cited authorities. Consequently, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

TOWNSEND & BANTA

A handwritten signature in black ink, appearing to read "Donald E. Townsend", written in a cursive style.

Donald E. Townsend
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